

EXHIBIT 2

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

**IN RE: PHILIPS RECALLED CPAP, BI-LEVEL
PAP, AND MECHANICAL VENTILATOR
PRODUCTS LIABILITY LITIGATION**

)
)
) **Case No. 2:21-mc-01230-JFC**
) **MDL No. 3014**
)
) **Honorable Joy Flowers Conti**

**THIS DOCUMENT RELATES TO: ALL
PERSONAL INJURY CASES**

DEFENDANT FACT SHEET

Defendants Philips RS North America LLC f/k/a Respironics, Inc. (“Philips RS”); Koninklijke Philips N.V.; Philips North America LLC; Philips Holding USA, Inc.; and Philips RS North America Holding Corporation (collectively “Defendants”) hereby submit the following Defendant Fact Sheet (“DFS”) responses.

Defendants conducted reasonable searches of their business records for information and/or documents responsive to each DFS request using the information Plaintiff provided in their Plaintiff Fact Sheet (“PFS”). As such, the DFS will be completed following completion of the PFS.

INSTRUCTIONS

Defendants must complete this DFS and identify by production bates number or provide documents and/or data relating to each Plaintiff responsive to the questions set forth below to the best of Defendants’ knowledge. Defendants are not required to provide documents or data that are exclusively located in the custodial files of individual sales and marketing representatives. Searches for responsive case-specific documents in the custodial files of relevant sales and marketing representatives shall be the subject of a separate order concerning discovery for bellwether cases. The DFS shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order.

A completed DFS shall be considered discovery responses pursuant to Fed. R. Civ. P. 33 and 34 and will be governed by the standards applicable to written discovery under the Federal Rules of Civil Procedure. You must supplement your responses as provided by and in accordance with Fed. R. Civ. P. 26(e). The questions and requests for production of documents contained in this DFS are non-objectionable and shall be answered without objection. This DFS shall not preclude Plaintiffs from seeking additional documents and information on a reasonable, case-by-case basis, pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order(s), subject to the Court’s determination.

In completing this DFS, you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all the details requested, provide as much information as you can.

In the event the DFS does not provide you with enough space for you to complete your responses or answers, attach additional sheets if necessary.

This DFS must be completed and served on counsel of record representing the Plaintiff(s) in the action identified in Section I below. This must be answered and served by the date established by the Court in the Case Management Order implementing this DFS.

DEFINITIONS

DEFENDANT(S): As used herein, the term(s) Defendant(s) means Philips RS North America LLC f/k/a Respironics, Inc. (“Philips RS”); Koninklijke Philips N.V.; Philips North America LLC; Philips Holding USA, Inc.; and Philips RS North America Holding Corporation, and any officers, agents, attorneys, employees, representatives, contractors, or others acting on their behalf.

YOU, YOUR or YOURS: As used herein, the terms “you”, “your” or “yours” mean the responding Defendant(s) and any officers, agents, attorneys, employees, representatives or others acting on Defendant’s behalf.

DEVICE(S): As used herein, the terms “device” or “recalled device” or “device(s)” mean and refer to the Philips CPAP, BiPAP, or mechanical ventilator device(s) that is the subject of Plaintiff’s complaint in the above-referenced action.

DME: As used herein, the term “DME” means a durable medical equipment provider or supplier.

DOCUMENT(S): As used herein, the terms “documents”, “document”, or “documentation” shall be construed in the broadest sense, consistent with Federal Rules of Civil Procedure 34(a)(1)(A), and shall mean and refer to documents, electronically stored information and tangible things and shall have the broadest possible meaning and interpretation ascribed to those terms, whether printed or recorded or reproduced by any other mechanical process, or written or produced by hand: agreements, “communications”, state and federal governmental hearings and reports, correspondence, telegrams, memoranda, summaries or records of telephone conversations, summaries or records of personal conversations or interviews, diaries, graphs, reports, notebooks, note charts, plans, drawings, sketches, maps, summaries or records of meetings or conferences, summaries or reports of investigations or negotiations, opinions or reports of consultant, radiographs, photographs, motion picture films, brochures, pamphlets, advertisements, circulars, press releases, drafts, letters, any marginal comments appearing on any document, and all other writings.

HEALTHCARE PROVIDERS: As used herein, the terms “healthcare provider” or “healthcare providers,” and abbreviation “HCP” mean and refer to all persons and, their respective medical

offices, identified in the PFS who prescribed and/or treated Plaintiff related to the Device(s) identified in the PFS.

PLAINTIFF: As used herein, the terms “Plaintiff” or “Plaintiff’s” refer to the Plaintiff identified in Section I below who used the Device(s).

RECALL: As used herein, the term “recall” means and refers to Defendants’ recall, announced on June 14, 2021, as such has been amended and expanded, of certain prescription medical devices, including CPAP, BiPAP, and mechanical ventilator devices, due to potential health risks related to PE-PUR sound abatement foam used in the devices. *See Recall Notice, available at:* <https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-soundabatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html>.

CALL NOTES: As used herein, the term “call notes” refers to any document, communication, record, or note reflecting contacts or communications between Defendants and any of Plaintiff’s Healthcare Providers or DME related to Defendants’ Devices.

COMMUNICATION AND/OR CORRESPONDENCE: As used herein, the term “communication” and/or “correspondence” shall mean and refer to any oral, written, or electronic transmission of information, including, without limitation, meetings, discussions, conversations, telephone calls, memoranda, letters, e-mails, text messages, conferences, or seminars or any other exchange of information between you and any other person or entity.

KEY OPINION LEADER or THOUGHT LEADER: As used herein, the terms “key opinion leader” or “thought leader” shall mean and refer to any scientist, engineer, doctor, or medical professional that Defendant(s) compensated, hired, retained, and/or contracted or consulted with, or retained to, amongst other things, consult; give lectures or presentations; respond to media inquiries conduct or participate in any study, trial, or investigation; author or contribute to articles or abstracts; sit on advisory boards; and/or make presentations on behalf of any Defendant at regulatory meetings or hearings.

MARKETING: As used herein, the term “marketing” shall mean any and all efforts to assist in the distribution and/or sale of devices. Marketing includes documentation, communications, and electronically stored information designating particular campaigns, promotional material and/or other promotional efforts directed toward particular types or specialties of healthcare providers.

SALES REPRESENTATIVE: As used herein, the term “sales representative” shall mean any person presently or formerly engaged or employed by Defendant(s) whose job duties include(d) calling on physicians or other healthcare professionals, healthcare facilities, hospitals, physician practice groups, or other prescriber, seller, or distributor for the purpose of promoting Device(s).

RESEARCH & DEVELOPMENT: As used herein, the terms “research and development” or “R&D” shall mean efforts, investigations, and/or projects, whether scientific or otherwise, to develop new and/or different types of products, processes, or designs of pre-existing products and is meant to incorporate all efforts that specifically contemplated the possible alteration of products.

HEALTH HAZARD(S): As used herein, the term “health hazard(s),” shall refer and relate to any injury, effect, damage, scarring, wound, impairment, or disability of any part of the human anatomy, including but not limited to the lungs and lung linings.

I. CASE INFORMATION

This Defendant Fact Sheet pertains to the following case:

Case Name:	
Case Number:	
Plaintiff Counsel:	
Date completed:	
Date supplemented:	

II. DEVICE INFORMATION

1. Provide the Date of Manufacture, the Date of Release, the Date of Sale of Plaintiff's Device, and identify to whom the Device was sold if not directly to Plaintiff.

Alternatively, you may respond with specifically segregated documents that provide the below information, and either (a) attach same to your response hereto, or (b) produce such segregated documents to a designated MDL centrality folder/directory and provide in your response hereto the Bates number(s) specific to Plaintiff's information.

Device	Date of Manufacturing	Date of Release	Date of Sale	Sold To

III. DEVICE RECALL INFORMATION

1. Was Plaintiff's device part of the recall?

If yes, please identify the following:

Device	Recalled (Yes/No)	Date of Recall

2. Was Plaintiff's device returned to Defendants?

If yes, please identify the following. Alternatively, you may respond with specifically segregated documents that provide the below information, and either (a) attach same to your response hereto, or (b) produce such segregated documents to a designated MDL centrality folder/directory and provide in your response hereto the Bates number(s) specific to Plaintiff's information.

Device	Returned to Defendants (Yes/No)	Date Defendants obtained possession or control of Device	Current location of the device	Bates number of all photographs of Plaintiff's device	Bates number of all data downloaded from Plaintiff's device

Device	SD card included in return?	SD card preserved?	Device Status (check one)	Describe any testing or evaluation conducted on Plaintiff's device
			<input type="checkbox"/> : Stored <input type="checkbox"/> : Retrofitted and returned to service <input type="checkbox"/> : Disposed due to: _____ <input type="checkbox"/> : Other: _____	

3. Identify the labels, user manuals, instruction for use, and warranties that accompanied Plaintiff's device, including the time period that each was in effect. Alternatively, you may respond with specifically segregated documents that provide the below information, and either (a) attach same to your response hereto, or (b) produce such segregated documents to a designated MDL centrality folder/directory and provide in your response hereto the Bates number(s) specific to Plaintiff's information.

IV. CONTACTS WITH HEALTHCARE PROVIDERS/DMEs

As to each Healthcare Provider and/or DME identified in Plaintiff's PFS, provide the following information. Alternatively, for each question, you may respond with specifically segregated documents that provide the below information, and either (a) attach same to your response hereto, or (b) produce such segregated documents to a designated MDL centrality folder/directory and provide in your response hereto the Bates number(s) specific to Plaintiff's information.

1. Identify the sales representatives (direct employee and/or employee of third party sales representative agent) who were assigned to the territory for the Healthcare Provider and/or DME identified in the PFS for Plaintiff's Device including the time period the sales representative worked within the applicable territory.

<i>Insert Name of HCP or DME</i>				
Sales Representative	Territory	Time Period	Immediate Supervisor and Title	Employment Status

2. Provide the details of each contact between You and each of Plaintiff's Healthcare Providers and/or DMEs identified in the PFS, including the date of each contact, the identity of Defendants' employee/representative/agent involved, the name of the Healthcare Provider and/or DME involved, the address of the facility or location where the contact occurred, the nature of the sales detail or communication, and the product or issue discussed.

<i>Insert Name of HCP or DME</i>			
Date of Contact	Product at issue	Representative Involved	Nature of communication/contact

3. Identify all communications regarding the health hazards, potential health hazards, or safety of Plaintiff's device, including each Dear Doctor, Dear Healthcare Provider, Dear Colleague communication or complaint file(s) for Plaintiff's device reflecting communications with Plaintiff's Healthcare Providers and/or DMEs relating to the safety or efficacy of Defendants' product(s).

<i>Insert Name of HCP or DME</i>			
Date	Addressee of communication	Bates Number of communication	Health Hazard or Device at Issue

4. Identify each piece of marketing literature and/or brochure or sales collateral that has been provided or made available to, or used with, any of Plaintiff's Healthcare Providers and/or DMEs.

<i>Insert Name of HCP or DME</i>	
Device	Bates Number of marketing literature/sales collateral

5. If you have ever had a financial relationship with, or provided compensation or remuneration in any form to, any of Plaintiff's identified Healthcare Professionals and/or DMEs, whether direct or indirect, complete the following or produce documents sufficient to identify the date of each such payment/compensation, the amount of such payment/compensation, and the nature and details of the service, work, or good attendant to such payment/compensation.

<i>Insert Name of HCP or DME</i>		
Date of Payment	Amount of Payment	Nature of service/work

6. For Plaintiff's Device, identify any training provided to or by the Healthcare Provider and/or DME; including but not limited to date, location, physician's role, cost for attending such training and subject matter.

V. INFORMATION REGARDING THE PLAINTIFF

1. Have you been contacted by Plaintiff, any of his/her Healthcare Providers and/or DME, or anyone on behalf of Plaintiff concerning the Plaintiff? If so, please provide the following information. Alternatively, you may respond with specifically segregated documents that provide the below information, and either (a) attach same to your response hereto, or (b) produce such segregated documents to a designated MDL centrality folder/directory and provide in your response hereto the Bates number(s) specific to Plaintiff's information.:
 - a. The name of the person(s) who contacted you;
 - b. The person(s) who were contacted including their name, address and telephone number; and
 - c. Identify any and all documents which reflect any communication between any person(s) and you concerning Plaintiff.

Name of contact	Date of contact	Address/Phone number of contact	Bates Number

2. Identify all data, information, objects, and reports in Defendants' possession or control, or which have been reviewed or analyzed by Defendants, with regard to the Plaintiff's medical condition; this also includes but is not limited to any study or research that includes Plaintiff's specific Device or associated lot/serial number. Attorney-work product is specifically excluded from this request.

VI. ADVERSE EVENT REPORTS/MEDWATCH REPORTS

Have you reported any adverse experience or events related to Plaintiff to any regulatory authority? If so, provide the following information. Alternatively, you may respond with specifically segregated documents that provide the below information, and either (a) attach same to your response hereto, or (b) produce such segregated documents to a designated MDL centrality folder/directory and provide in your response hereto the Bates number(s) specific to Plaintiff's information.

Adverse Event Report Date	Regulatory Authority	Identification number	Employees/Representatives involved	Bates Number

VII. DOCUMENT REQUESTS

Please ensure that the production of documents includes specific reference to the question to which the document(s) is provided in response.

To the extent you have produced through MDL Centrality or attached to this DFS the documents requested below in responding to the above questions, the documents do not need to be produced again.

1. Identify and produce complete documentation of all information set forth above, including any and all documents reviewed, referred to or relied on in answering this DFS, except, you may identify but not serve copies of medical records that were provided to Defendants by Plaintiff's counsel.
2. Produce a true and complete copy of the Device History Record for the Plaintiff's lot/serial number(s), which includes the date of manufacture, the place of manufacture, the date when the manufacturing process began and the date on which the device was released for sale.
3. Produce the adverse event information relating to the Plaintiff, including, identification of the relevant PR#; documents relating to the Plaintiff that pre-existed the filing of this action; and Copies of any MedWatch forms submitted to the FDA with regard to the Plaintiff.
4. Produce any photographs, evaluation, studies, or other documents relating to Plaintiff's Device, including the condition, storage, and testing of Plaintiff's Device, Plaintiff's SD card, including all available identifying information including the dates, and who took the photographs or conducted the testing on Plaintiff's Device.
5. Produce all documents relating to Plaintiff's use of the device including any documents created by Plaintiff's use of Defendant's DreamMapper application or other method of tracking device use.
6. Produce all communications between the Defendants, the sales representative company and/or sales representative(s) identified above and Plaintiffs Healthcare Provider(s) and/or DME about any device(s), including but not limited to general correspondence, device related correspondence, telephone or email contacts, meetings, or sales literature.
7. Produce all Call Notes relating to Plaintiff's identified Healthcare Provider(s) and/or DME(s), including all call notes, detail notes, call summaries, entries made by sales representatives into any database or e-room, laptop or other computer or handheld device, hard copy documents, emails and/or notes or records or summaries of calls, contacts and/or communications of any kind regarding each device or physician for Plaintiff during the relevant time period.
8. For each Device identified by Plaintiff, produce a copy of the complaint file(s), including any and all medical records, if any.

9. Produce documents which reflect communications between Plaintiff or anyone acting on Plaintiff's behalf (other than Plaintiff's counsel) and Defendant concerning Plaintiff's device or medical condition, including any script used for telephone communications, and summaries or notes of any communication between Plaintiff and Defendant, as well as all information stored in the Patient Portal related to Plaintiff's Device.
10. Aside from any privileged materials, identify and attach all records, documents, and information that refer or relate to the Plaintiff to the extent not identified and attached in response to a prior question.

VERIFICATION

My name is _____ and I am ____ (Role) for [INSERT ANSWERING DEFENDANT NAME] (“Defendant”). In this role I am responsible for the collection of certain information and documents on Defendant’s behalf. The foregoing answers were prepared with the assistance of a number of individuals, including counsel for Defendant, upon whose advice and information I relied. I declare under penalty of perjury that all the information as to Defendant provided in this Defendant Fact Sheet is true and correct to the best of my knowledge upon information and belief, and that I am authorized by Defendant to make this verification on its behalf based upon my role in this action as set forth above.

[SIGNATURE]

[PRINTED NAME]

[DATE]